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## Human guinea pigs

What you need to know before entering a clinical trial:  
You are not a patient

If you are considering volunteering for a clinical trial, you can help ensure your safety by understanding some of the basic tenets of medical research, the first of which is that medical *research* is far different from medical *care*.

Medical care is based on the assumption that a doctor sees a patient as an individual and tailors one-on-one treatment. In medical research, doctors and scientists design a study, called a protocol, to which all volunteers must rigidly adhere, regardless of the characteristics of any single patient. "It's not the doctor's best judgment of what's best for *you*," says George Annas, chairman of the health law department at Boston University School of Public Health. Rather, a trial serves the ends of science.

Most of the money for clinical trials, both public and private, goes to research on cancer and AIDS. But human experiments also test potential treatments for hundreds of other diseases, from psoriasis to glaucoma, from osteoporosis to clogged arteries. The Web site of the National Institutes of Health ([www.nih.gov/health/trials/index.htm](http://www.nih.gov/health/trials/index.htm)) offers the most complete list of clinical trials. Support groups for specific diseases may have further information.

Whatever the trial, you should find out what questions researchers hope to answer in their study. The issue could be, for example, whether lung reduction surgery has a better outcome for people with emphysema than, say, treatment with bronchodilator drugs. You must be prepared to accept either surgery or drugs, based not on your preference but on the luck of the draw.

You should ask researchers how many others in the trial have been tested, how many people the trial needs, and what has happened to participants. For example, Phase II trials, which test whether a treatment that has been deemed safe actually works, are designed around probabilities: Researchers decide they need a certain number of patients, say 20, to prove that



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For information on cancer trials, try the National Cancer Institute.

CenterWatch is a listing service for clinical trials. It has information for potential participants in

a treatment is ineffective. If 19 patients have been treated, and you are patient No. 20, clearly you should ask whether the treatment worked on your predecessors. If it was not effective for all 19, researchers still need a 20th patient to complete the trial. Researchers would not be obliged to tell patients that the trial didn't work for the first 19 people, since they would only *suspect* the treatment was ineffective. Still, you should expect an honest answer if you ask directly how others have fared.

clinical trials.

**Second opinions.** Physicians involved in clinical research must present detailed information about risks to patients and make themselves available for questions before patients sign the required informed-consent documents. Research assistants, nurses, and others can also answer questions. But patients should also get a second opinion, advises Alexander Capron, professor of law and medicine at the University of Southern California. "Get information from someone with no stake in the research," he says, because doctors doing the research may be too close to the project to be completely objective.

If you still have concerns after enrolling in a research trial, you can talk to the lead researcher of the trial, who is likely to know the most about the project; the chair of the institutional review board, the group that oversees all human research in an institution; or the hospital's ombudsman. If you don't get satisfaction, you can contact the Office for Protection From Research Risks at the nih ([www.nih.gov/grants/oprr/oprr.htm](http://www.nih.gov/grants/oprr/oprr.htm)).

Your most important right as a tester of unproven drugs and treatments is that you can drop out of a clinical trial at any time, for any reason—or for no reason at all.—  
*Susan Brink*

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